Trial

Title: Proving causation in breast-cancer cases.

Summary: The delay of three months in the diagnosis of breast cancer can strongly impact treatment and long-term survival.

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Trial

Proving causation in breast-cancer cases.

Misdiagnosis of breast cancer is one of the most often reported medical negligence allegations. Expeditious diagnosis and treatment of malignancies can prevent lost opportunities for cure or effective palliation. If treatment is delayed, the patient may need much more extensive surgery, radiation therapy, or chemotherapy--all of which may have been unnecessary if treatment had been rendered earlier.

There are several types of breast cancer. They all have one thing in common: Abnormal cells grow and destroy body tissue. In its simplest form, breast cancer is one cell gone bad. While healthy cells that make up the body's tissue grow, divide, and replace themselves in an orderly way--keeping the body in good repair--some cells lose the ability to control their growth. These cells grow too rapidly and without any order. Too much tissue is made and tumors are formed.

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Tumors can be malignant or benign. Malignant tumors are cancerous; benign tumors are not. Malignancies can invade and destroy nearby healthy tissues and organs.

Cancer cells can also break away from the original or primary tumor and enter the bloodstream or lymphatic system--the tissues and organs that produce and store cells that fight infection and the channels that carry lymph fluid. This is how cancer spreads to other parts of the body. If this spreading, called metastasis, has occurred, even if the primary tumor is removed from the breast, the disease remains in the area to which it has spread. Progressive growth of metastasis will result in destruction of vital organs, and the patient will die.

Although the cause of breast cancer remains unknown and a practical means of prevention is not at hand, detecting the disease while it is still localized is the key to successful treatment. Oncological experts I have worked with say that because there are several techniques available for early detection, better than two-thirds of women with some form of breast cancer are cured of the disease. For this reason, misdiagnosis or delay in diagnosis is the most significant area of negligence in breast cancer cases.

Diagnosis

There is only one method of making a definitive diagnosis of breast cancer--histologic examination of tissue. This is a microscopic look at the tissue to examine cell structure and determine whether the cells are cancer. There are, however, many techniques for detecting symptoms of the disease.

The initial symptoms of breast cancer are varied. In order of frequency, they include discrete lump; swelling; pain; nipple retraction; nipple bleeding, discharge, or crusting; skin puckering; and lump in the axilla (underarm).(1)

A patient with any of these symptoms requires proper diagnostic workups to determine the source of the problem. Nipple discharge, for instance, may or may not be caused by breast cancer. A physician who discovers a nipple discharge must diagnose its cause. If the doctor fails to rule out cancer, the standard of care has been breached.

Techniques available for early diagnosis include the following:

* Palpation is careful feeling of the breast to determine if a lump is present. If there is a lump, palpation can help determine its size, its texture, and whether it is movable.

* Mammography is an X-ray of the breast. Usually, a woman has two mammograms of each breast, one taken from the side and one from the top. Cancers can be detected earlier by mammography than by any other noninvasive means.

* Ultrasonography is a test that bounces sound waves off tissues and converts the echoes into pictures. Tissues with different densities reflect sound waves differently, making it possible to tell the difference between a fluid-filled cyst and a solid mass. Ultrasound is used in

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special situations to complement physical examination and mammography. It is noninvasive and does not involve radiation exposure.

* Computerized tomography (CT) scanning of the breast is relatively new and is still under evaluation. A CT scan does not replace a conventional mammogram in evaluating breast disease. It does, however, give the physician a view of both the axillary and the internal mammary lymph nodes, and it provides an excellent picture of the tissues in and behind the breast.

* Thermography is used to measure and create an image of heat patterns on skin. Cancer ordinarily produces more heat than surrounding tissues because of its high metabolism. If this heat is transmitted

to the skin directly or through veins draining the cancer, it can produce abnormal surface heat. Since the value of thermography as a way to detect breast cancer remains unproved, it is not routinely used in evaluating the breast.

* Aspiration involves use of a thin needle to remove fluid or a small amount of tissue from a breast lump. This may show whether the lump is a fluid-filled cyst (which is not cancer) or a solid mass (which may or may not be cancer).

* Biopsy is the process of removing tissue for diagnostic examination. A diagnosis can be made with confidence only when the tissue is examined under a microscope. A negative biopsy can be due to sampling error, so cancer cannot be excluded unless all pathologic tissue is removed and examined thoroughly.

Generally, biopsy is appropriate if the patient has a persistent mass or dominant nodule, a persistently discharging duct, unexplained nipple changes, or an abscess or unexplained inflammatory signs. Biopsy is also indicated when results of a mammogram are suspicious.

With so many diagnostic techniques available, it is inexcusable for a physician with a symptomatic patient to fail to diagnose or rule out breast cancer.

In every case, the most significant issue is whether the delay in diagnosis or the misdiagnosis caused damage to the patient. Did the physician's breach of the standard of care make the patient's plight worse than it would have been had the proper diagnosis been made earlier?

Physicians define causation in these cases as a change in the characteristics or stage of the tumor as a result of the delay. These changes result in more extensive or invasive treatment and may reduce the patient's chance of long-term survival.

Defense experts and physicians not truly knowledgeable in the field will say there is no causation when the delay in diagnosis is less than six months. This is why lawyers reviewing these cases must be familiar with the medical literature to fulfill their duty to clients.

Numerous studies have correlated the duration Of symptoms with five-year survival after treatment. There is clear evidence that when diagnosis after the first symptoms appear is delayed more than three months, cancers tend to be larger and more aggressive.(2) Large tumor

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size, the presence of metastasis in the axillary lymph nodes, and advanced clinical stage are all associated with a poor prognosis. Each of these characteristics becomes more prevalent the longer treatment is delayed. Stage of disease at diagnosis is the most important factor in determining the probability of long-term survival.(3)

The burden of proving causation differs from jurisdiction to jurisdiction. In some states, the plaintiff must prove that as a result of the physician's breach, it is more likely than not that she has a reduced life expectancy.(4) This means a plaintiff must prove that the failure to diagnose prevented cure or resulted in a substantial loss of life expectancy. Other jurisdictions recognize the loss-of-chance doctrine, which allows a cause of action when the patient can prove she has lost the opportunity to avoid physical injury, disease, or death. Typically, these cases involve a failure to diagnose and treat breast cancer in a timely fashion.

The traditional standard of causation requires proof, in terms of probability, that the defendant's conduct did, in fact, proximately cause the plaintiff's injuries or death. For example, one medical malpractice case involved a boy who was struck by a truck and taken to the emergency room of a local hospital, where he complained of a headache and vomited. The physician failed to diagnose a fractured skull and instead released the boy, who died the next day from intracranial hemorrhaging.

Suit was filed against the physician for failure to diagnose. According to the plaintiff's expert, the boy would have had a chance of recovery if he had had surgery. However, the expert was unable to state that it was more likely than not (that there was a greater than 50 percent certainty) that the boy would have survived with surgery. The Ohio court affirmed a judgment for the defendants on the ground that the plaintiff could not establish that the physician's negligence had proximately caused the boy's death.(5)

A later case in Ohio accepted the loss-of-chance theory.(6) The rationale underlying this theory is that the traditional standard of causation may unjustly deprive a plaintiff of recovery even when the physician is blatantly at fault. As one court explained,

the health care professional should not be

allowed to come in after the fact and allege that

the result was inevitable inasmuch as that

person put the patient's chance beyond the

possibility of realization. Health care

providers should not be given the benefit of the

uncertainty created by their own negligent

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conduct. To hold otherwise would in effect

allow care providers to evade liability for their

negligent actions or inactions.(7)

Most courts hold that once the plaintiff proves the defendant has increased the risk of harm by depriving the patient of a chance to recover, the case can go to the jury on the causation issue regardless of whether the plaintiff could prove to a degree of medical probability that the defendant caused the patient's injury or death.(8) Although the plaintiff still has the burden of persuading the jury by a preponderance of the evidence that the defendant brought about the harm the patient suffered, the jury, rather than the medical expert, is given the task of balancing the possibilities.

Cancer staging

To prove causation, the attorney must establish the extent of cancer at the time of misdiagnosis. This is called staging. Its purpose is to define the stage of the cancer so that comparisons can be made in terms of prognosis and treatment. The stage of the cancer determines whether metastasis was probable at the time of misdiagnosis and what the resulting prognosis and treatment options were then, as opposed to what they were at the time the malpractice was discovered.

The physician will determine the stage of cancer when the disease is first diagnosed. This process is called clinical staging. Pathological staging occurs when the tumor has been surgically removed and the extent of the malignancy determined microscopically. Pathological staging is more accurate than clinical staging.

The American Joint Committee on Cancer of the American Medical Association has classified the stages of cancer:

* Carcinoma in situ is very early breast cancer. Cancer is found in a local area and in only a few layers of cells.

* Stage I means the tumor is no larger than two centimeters--about an inch--and has not spread beyond the breast.

* Stage II means the tumor measures from two to five centimeters--about one to two inches-and/or has spread to the lymph nodes in the underarm.

* Stage III means the cancer is larger than five centimeters. It involves more of the underarm lymph nodes, and/or it has spread to other lymph nodes or other tissue near the breast.

* Stage IV means the cancer has spread to other organs of the body, most often the bones, liver, lungs, or brain.

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Most patients at Stage I are cured with proper care and treatment.(9) The simple reason is that the cancer has not spread. For most types of cancer, the extent to which the disease has spread is probably the most important factor determining prognosis and must be given prime consideration in evaluating and comparing different treatments.

As tumor size increases, the chance for lymph node involvement or metastasis increases and survivability decreases. Breast cancer spreads directly to the bloodstream as well as to the draining lymphatics. As the primary tumor grows, cancer cells invade the local area surrounding the tumor, then spread to the regional lymph nodes draining the area of the tumor. It is usually later that distant spread or metastasis becomes evident from clinical examination.

Attorneys can determine the extent of the cancer when it was diagnosed by looking for three key findings in clinical examinations: size of underlying tumor, spread to primary lymph nodes, and metastasis.

The lawyer must find a highly competent oncologist who can testify to the stage of the cancer when the diagnosis should have occurred and the stage of the cancer at the time of correct diagnosis. The difference will enable the oncologist to determine any damage caused by the delay.

To meet the burden of proof on causation, the lawyer must show that the patient had cancer at the time of misdiagnosis. The lawyer must then prove that the changes that occurred between the misdiagnosis and the correct diagnosis made a significant difference in treatment and prospects for long-term survival.

Since measurements of tumor size will have been done only when the biopsy was performed and the disease accurately diagnosed, the expert must undertake a clinical staging of the disease at the time of misdiagnosis. The expert can do this by measuring the tumor as shown on a mammogram taken at the time of misdiagnosis or by reviewing results of other diagnostic tests.

When there are no diagnostic test results from the time of misdiagnosis, proving causation will be more difficult. But there are steps the lawyer can take.

If the time between misdiagnosis and diagnosis is long enough, the literature and scientific studies may be sufficient to establish causation. The expert may rely solely on scientific studies to document a significant change in the extent of the disease.

However, if the time between misdiagnosis and diagnosis is short--six months to a year--the attorney may turn to a theory called doubling time. Doubling time is how long it takes for a malignant tumor to double its number of cells. This method is sometimes used to estimate how long a patient had the disease before diagnosis.(10)

The problem with using this theory is that it depends on a variety of factors that influence tumor growth. Most often, doubling time will be used by the defense to confuse the causation issue.(11)

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A better way to establish the extent of breast cancer at the time of misdiagnosis is to establish the size of the tumor in the lymph nodes at the time the biopsy was performed. The lawyer may wish to obtain the services of a pathologist-oncologist to examine the tissue slides from the biopsy when the disease was diagnosed.

When breast cancer metastasizes, the tumor invades the lymphatic channel and literally flows to a nesting site in the lymph nodes. The diameter of the tumor nodules in the lymph nodes can be measured to determine the tumor's mass. This enables the expert to work from physical evidence with a clear knowledge of what the minimal time requirement would be for metastasis to occur. It also enables the expert to determine how many nodes were involved at any time. In a loss-of-chance case, the number of nodes involved relates directly to the probability of long-term survival.

Most malpractice cases involving late diagnosis of breast cancer are defended on the issue of causation. When investigating a failure-to-diagnose case, the trial attorney must understand how breast cancer grows and spreads, as well as how physicians diagnose and treat it. The key for the lawyer will be to develop proof that will show the jury how the misdiagnosis made the difference in the patient's treatment and prospects for long-term survival.

Notes

(1.) Yorkshire Breast Cancer Group, Symptoms and Signs of Operable Breast Cancer, 1976-1981, 70 BRIT. J. SURGERY 350 (1983).

(2.) See generally JAY R. HARRIS ET AL., DISEASES OF THE BREAST chs. 12, 16 (1996).

(3.) H.J. Bloom, The Influence of Delay on the Natural History and Prognosis of Breast Cancer: A Study of Cases Followed for Five to Twenty Years, 19 BRIT. J. CANCER 228 (1965).

(4.) The feminine pronoun is used throughout this article because the vast majority of people with breast cancer are women. It is possible, however, for the disease to develop in men.

(5.) Cooper v. Sisters of Charity, Inc., 272 N.E.2d 97 (Ohio 1971).

(6.) Roberts v. Ohio Permanente Med. Group, Inc., 668 N.E.2d 480 (Ohio 1996).

(7.) McKellips v. St. Francis Hosp., Inc., 741 P.2d 467, 474 (Okla. 1987).

(8.) See RESTATEMENT (SECOND) OF TORTS [sections] 323 (1965); see also Hamil v. Bashline, 392 A.2d 1280, 1286-88 (Pa. 1978); Herskovits v. Group Health Coop., 6654 P.2d 474 (Wash. 1983).

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(9.) J.S. Spratt Jr. et al., Cytokinetic Definition of Acute and Chronic Breast Cancer, 37 CANCER RES. 226 (1977).

(10.) 1 MELVIN A. SHIFFMAN ET AL., ATTORNEYS' GUIDE TO ONCOLOGY CASES 76 (1994).

(11.) Ronald Citron, Late Cancer Diagnosis: The Myth of Doubling Time, TRIAL, May 1991, at 54.

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